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Judge Refuses to Hear Expert Testimony on Tylenol Link to Autism, ADHD

The 440 lawsuits brought against Tylenol and generic acetaminophen manufacturers do not have "admissible evidence" to show that prenatal exposure to the medication can lead to autism spectrum disorder or attention-deficit/hyperactivity disorder, a federal judge ruled this week.

By **Suzanne Burdick, Ph.D.**

34

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The 440 lawsuits brought against Tylenol and generic acetaminophen manufacturers do not have "admissible evidence" to show that prenatal exposure to the medication can lead to autism spectrum disorder (ASD) or attention-deficit/hyperactivity disorder (ADHD), a federal judge ruled this week.

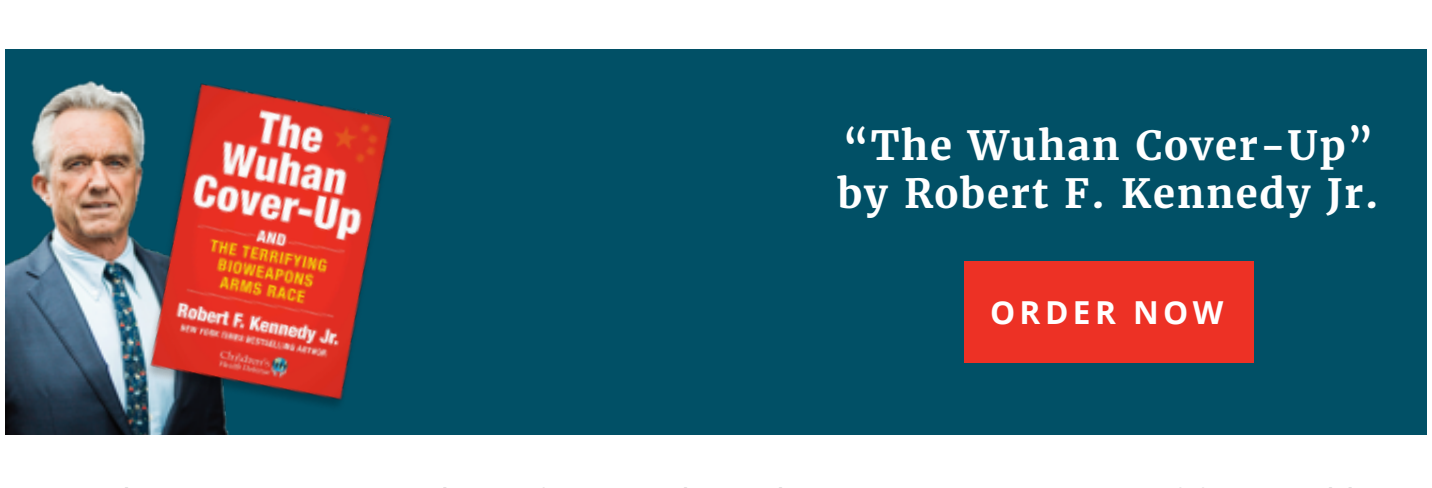
The news comes as a blow to the hundreds of families who filed lawsuits alleging their child developed ASD and/or ADHD as a result of the mother taking acetaminophen during the pregnancy.

U.S. District Judge Denise Cote in the Southern District of New York, who is presiding over the cases, in her 148-page opinion wrote that, in the absence of admissible evidence, the District Court will not hear the plaintiff's expert testimony.

The ruling "effectively kills" the consolidation of lawsuits, Bloomberg reported. The Defender asked lawyers with four of the main firms handling the cases for comment, but they did not respond by our publication deadline.

The lawsuits allege retailers, including Walmart, CVS, Walgreens and others, falsely advertised products that contain acetaminophen as being safe for pregnant women and did not warn them about the risks posed to fetal development.

Johnson & Johnson's former consumer health unit, now a separate company called Kenvue, told Reuters in a statement it will move to dismiss the lawsuits in light of the ruling. Johnson & Johnson, the original maker of the Tylenol brand, was not named in the suits.



Since the mounting number of cases shared common questions of fact and law regarding the adequacy of the Tylenol pregnancy warnings, the U.S. Judicial Panel on Multidistrict Litigation (JPML) in late 2022 centralized all the lawsuits brought throughout the federal court system into federal multidistrict litigation (MDL) brought before Judge Cote.

Commenting on the court's latest decision, Brian Hooker, Ph.D., Children's Health Defense senior director of science and research, told The Defender:

> "The judge has ignored a mountain of evidence in order to genuflect to Johnson & Johnson by denying the plaintiff's expert testimony to move forward. This essentially denies justice to the many families with ASD children and is a slap in the face to the developmental disability community in general."

Meanwhile, William Parker, Ph.D. — who for the last 10 years has researched acetaminophen risks — said the judge's ruling was "great" because "it gets us one step closer to figuring out when the drug causes neurological disorders like ASD so we can 1) stop widespread acetaminophen use in the population most at-risk, and 2) hold those responsible accountable."

Pregnancy lawsuits could be a 'red herring'

Parker said that it is a "scientific fact" that many autism cases are induced by acetaminophen — but that this mostly happens once the baby is born, not while in utero. He told The Defender:

> "It would be horrible if this lawsuit moved forward because it could convince everyone that the induction of autism mostly happens during pregnancy. This could be a massive red herring, and could result in continued use of the drug in the pediatric — especially neonatal — population, which would be catastrophic."

Parker is a visiting scholar in the psychology and neuroscience department at the University of North Carolina, Chapel Hill, and the CEO of WPLab, a nonprofit that focuses on research and education about acetaminophen's impact on the developing brain.

He previously was a researcher at Duke University for 27 years and has authored more than 140 peer-reviewed articles.

Newborns, young kids most at risk

Based on Parker's read of the science on acetaminophen and health risks, he said a fetus is "pretty safe" during pregnancy compared to when the umbilical cord is cut.

"When you cut the umbilical cord, everything changes because you no longer have the mother's liver there to protect the fetus. The bottom line is that babies — especially freshly born babies, neonates, we call them — are not wired to process pharmaceuticals."

Parker said the judge's ruling did not surprise him because the lawsuits are narrowly focused on examining the scientific evidence of prenatal exposure to acetaminophen.

"I think that overall what I would have expected was exactly what that judge decided because, if you read her commentary, there's no peer-reviewed publication that says this is happening during pregnancy."

However, if the lawsuits had been about exposure to acetaminophen after birth, particularly shortly after birth, they would have had a firmer foundation of peer-reviewed studies on which to base their claims, he said.

For example, a 2022 peer-reviewed study proved that acetaminophen use in infants and children was never shown to be safe for neurodevelopment.

RFK Jr. and Brian Hooker's
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In June, Parker and colleagues published in the peer-reviewed journal Clinical and Experimental Pediatrics a review of studies on acetaminophen and neurodevelopmental injury in young kids, in which they concluded that "there is no valid rationale for controversy regarding the conclusion that early life exposure to acetaminophen causes neurodevelopmental injury in susceptible babies and small children."

Parker said the literature regarding a causal link between acetaminophen exposure and ASD is "clear" while the research on the causal link between the drug and ADHD is "more complex." He has focused his efforts on exposing how the drug causes ASD.

When used by adults, the drug is fairly safe under certain circumstances, Parker said. "For example, more than 50 million adult Americans use it every week, and, as a result, you get about two accidental deaths during the same time period."

"That's a very safe drug by most measures, but of course that applies only in adults," he added.

Plaintiffs: Tylenol should carry a warning

Before rendering her decision, Judge Cote earlier this year asked the plaintiffs' lawyers to propose an example of the acetaminophen pregnancy warnings that should have been provided to expecting mothers.

Products that contain the drug include Tylenol, Alka-Seltzer Plus, DayQuil, Excedrin, Goody's, Mucinex, NyQuil, Robitussin and some generic and store-brand equivalents.

In April, the lawyers sent a letter that included some of the existing language used on warning labels in Europe:

> "**Autism/ADHD:** Some studies show that frequent use of this product during pregnancy may increase your child's risk of autism and attention deficit hyperactivity disorder. If you use this product during pregnancy to treat your pain and/or fever, use the lowest effective dose for the shortest possible time and at the lowest possible frequency."

The lawyers said the defendants could have used this or different language to warn pregnant women about Tylenol autism risks.

Judge cites FDA review

Cote in April invited the U.S. government — particularly FDA regulators — to weigh in and then made a decision that aligned with the FDA's view. She wrote in her opinion:

> "Because this MDL raises important issues related to public health and drug safety for pregnant women and their offspring, the Court invited the United States, including the Food and Drug Administration ('FDA'), to submit its views on the Plaintiffs' Proposed Warning."

Cote asked the FDA to weigh in on two questions by July 28, or as soon thereafter as possible:

1. Should the Plaintiffs' Proposed Warning be added to acetaminophen labels?
2. As of today, does science warrant the addition to acetaminophen labels of any warning or advice regarding in utero exposure to acetaminophen and the risk of ASD or ADHD?

The FDA on July 28 sent a response letter, via Damian Williams, the U.S. Attorney for the Southern District of New York, saying the agency needed more time to put together its response. The same day, Cote extended the deadline to Sept. 15.

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A week before the deadline, the U.S. Department of Justice wrote to Cote, saying it had consulted with the FDA and the agency would not share its opinion on a potential risk label for Tylenol products.

The letter did, however, include the FDA's most recent review of pertinent studies. In her opinion, Cote wrote:

> "The Government declined to submit a Statement of Interest but noted in its letter the FDA's independent 2023 conclusion (discussed in more detail infra [Latin for 'below']) that the scientific evidence on this topic is as of yet 'unable to support a determination of causality.'"

Cote went on to cite the FDA's research and regulatory activities since 2014 on prenatal acetaminophen exposure and discuss the FDA's review of the three most recent studies on acetaminophen exposure in utero.

She cited the FDA's conclusion:

> "Overall, findings on the associations between APAP [acetaminophen] use during pregnancy and neurobehavioral and urogenital outcomes remain mixed.
>
> "The three studies reviewed here are limited and do not change DEPI-I's [the FDA's Division of Epidemiology I] conclusions from its most recent review — the limitations and inconsistent findings of current observational studies of APAP and neurobehavioral and urogenital outcomes are unable to support a determination of causality."

Cote concluded, "As the FDA's reviews of these studies have recorded time and again, the literature remains mixed."

It appears to have been beyond the scope of Cote's consideration if and to what extent industry influences may have interfered with the FDA's review.

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Suzanne Burdick, Ph.D.
Suzanne Burdick, Ph.D., is a reporter and researcher for The Defender based in Fairfield, Iowa.

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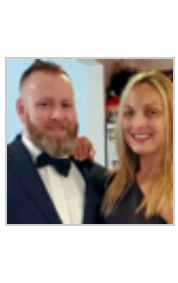

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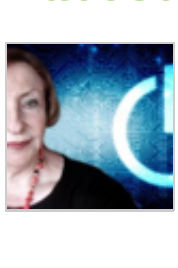

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holisticpoet
22 days ago
The elephant in the room here is that we know there is a problem, but how the law is manipulated to protect big pharma is more important than protecting our children. In a sane society everything that happens would be to protect our children first and foremost.
18 0 Reply • Share ›

> **rtj1211** ↗ holisticpoet
> 11 days ago
> You are of course right, but western societies now are very difficult places to work if you want to earn enough money to have children. You can't work in medicine, the law, teaching, the universities, the Civil Service nor the Armed Forces if you have ethical standards you won't compromise on.
> 0 0 Reply • Share ›

> **Darby O'Gill** ↗ holisticpoet
> 19 days ago
> Legalized abortion is proof that we do NOT have a sane society.
> 0 0 Reply • Share ›

Nod
22 days ago
All 3 branches of government are corrupt.
16 0 Reply • Share ›

> **tony** ↗ Nod
> 21 days ago
> Which is why we can't vote our way outta this Marxist mess. The left will do or say ANYTHING to maintain power while the right is paid to look away. They may talk a good game but all evidence points towards a uniparty.
> 4 0 Reply • Share ›

Barry Burton
22 days ago
It seems EXTREMELY CLEAR that the only Science being followed by nearly ALL PHARMACEUTICAL companies is now only POLITICAL SCIENCE.
It no longer matters how many bodies are maimed or destroyed by Pharmaceutical Manufacturers, so long as the Political Science brings more Profits, then they are following the Political Science and Safely making more profits. This makes everything safe for profits. So shut down the Courts and make sure the Judges are well paid.
11 0 Reply • Share ›

Chase Sheridan
22 days ago
Tylenol may be definitely be implicated in some cases of childhood autism, but I know of several families whose normal acting child began "acting different" within a few hours after their MMR. To have a chatty, giggling, happy, bright 5 year old suddenly become non-communicative, unable to speak, sullen, angry and unhappy within that MMR window, while being told their once delightful child was now seriously autistic and have it blamed on the genetics of the parents or plastic in the environment, or some other unrelated reason, even as the doctor noted the apparent onset of behaviors was right after the MMR is the definition of insanity. If a parent tries to attribute ANY unusual symptom or behavioral change to the MMR, they are made to feel like idiots.
10 0 Reply • Share ›

> **vgupta123** ↗ Chase Sheridan
> 22 days ago
> But did the baby also take Tylenol along with the MMR vax to alleviate the pain and fever that usually results from the shot? Some people take/give Tylenol even before the shot as a preventive measure.
> 3 0 Reply • Share ›

> **D.Plorable** ↗ Chase Sheridan
> 21 days ago
> Never correctly reported was the truth about Dr. Andrew Wakefield. Asked directly if he would vaccinate his own kids, he said "I would get the single-dose measles, not the MMR". The British Health immediately removed the single dose vax option and Merck quit making it--they put a memo on the CDC web page saying "after consulting with (unnamed) experts" they made this decision. Of course it was Merck that made piles of $ off AZT in league with Fauci as the only med that might work vs. AIDS. Last year I saw the exec who sits on top of Merck blandly state how even if they wanted to make the meds stateside, they couldn't because they outsourced the base components too!
> 2 0 Reply • Share ›

mangonanny
22 days ago
Why do people continue to file court cases in New York? Hasn't there been enough evidence by now that you cannot get a fair trial in that State? I wouldn't file a court case in any Democrat controlled state for that matter. More people must rise up and demand that these courts be investigated. Judges and Courts are NOT above the law. They cannot continue to ruin lives with impunity.
8 0 Reply • Share ›

> **Stephen Simac** ↗ mangonanny
> 16 days ago
> "Since the mounting number of cases shared common questions of fact and law regarding the adequacy of the Tylenol pregnancy warnings, the U.S. Judicial Panel on Multidistrict Litigation (JPML) in late 2022 centralized all the lawsuits brought throughout the federal court system into federal multidistrict litigation (MDL) brought before Judge Cote." They were filed around the country.
> 0 0 Reply • Share ›

Wendy Allen
22 days ago
If the mom takes drugs or shots while pregnant it may hurt the mom/baby. If the baby gets shots when less than 3 years old they may become Autistic due to shots with polysorbate 80 that lets the shot go into the brain. If the baby is given Tylenol....their liver may not work well and then in combo with shots allow the shots hurt more. GMO/Roundup may hurt in shots and food. Gluten may hurt the mom/babies gut lining so less nutrients absorb. Baby formula maybe 1/2 sugar that lowers the immune system/ may have GMO Corn with Roundup and GMO soy with Roundup. Breast feeding may help the baby if the mom is healthy and is absorbing enough nutrients by no gluten. A hair test shows good minerals/heavy metal levels. Shots may have Al/Hg (mercury) in them and cell lines/retro viruses etc..
5 0 Reply • Share ›

CastleConnell
22 days ago
Why did they go to court without peer reviewed studies on this? Taking any pharmaceutical during pregnancy is a risk because there are side effects. It seems very cruel to me to prescribe drugs to pregnant women, so many things can go wrong during this period of rapid growth. I think drugs should be limited to emergency or life/death situations, or cases that have to be managed, otherwise the risk outweighs their benefits. Pharma has such a grip on society as a whole. Going to a doctor and getting a prescription is normalized to the point where adverse effects are considered to only happen if you live on mars. Those who are risk aware are viewed as neurotic, and perhaps they are the more fearful types to begin with, but fear can be lifesaving too. It seems lawyers who become judges should have a degree in a biological science, to understand deeply what is at stake.
5 0 Reply • Share ›

truthseeker53
22 days ago
All lucifer's pharma's stuff is toxic. God gave us PLENTY of options. Sadly, some are illegalized by them, other's the sheeple don't have the initiative to learn about.
5 0 Reply • Share ›

lonerngr88
22 days ago
Unless the kids are un-vaccinated they will never be able to prove it was just the tylenol that caused the autism.
5 0 Reply • Share ›

> **Kimberly** ↗ lonerngr88
> 22 days ago
> My ASD kiddo is unvaccinated but the lawyers would not include him in any of the initial research because I gave birth to him after I turned 40!
> 4 1 Reply • Share ›
>
> > **Chelsea Thompson** ↗ Kimberly
> > 22 days ago
> > That's too bad. I'm sorry they did that. Good for you not vaccinating. Stay healthy and strong.
> > 4 0 Reply • Share ›
>
> > **D.Plorable** ↗ Kimberly
> > 21 days ago
> > Please consult Dr. Hyman's earlier book "Ultrametabolism" as he has excellent practical advice about diet and supplement solutions for kids like yours. Dr. Amen's multiple books and video presentations touch on this as well. For God's Sake don't let your child eat any "ultraprocessed" junk food as the stuff really is poison.
> > 2 0 Reply • Share ›
> >
> > > **Kimberly** ↗ D.Plorable
> > > 13 days ago
> > > Thanks for sharing- we are very careful about what goes into his mouth- he is gluten free (we don't replace gluten items with "gluten free" crap), we feed him organic and as local as possible.
> > > 0 0 Reply • Share ›

Wendy Allen
22 days ago
Some moms may give the baby Tylenol to bring down a fever from the shots which hurts the baby's liver so it can't detox well. There are too many shots...2 on day one of birth and 75 up to kindergarten and then more after that and more for jobs/military/college/travel etc..
Shots may burden the immune system and 7-8 shots at one time may kill a baby. Some syringes have 3 shots in them. Parents saw the child become hurt from the shots and within 2 weeks of the shot. The COVID shot may cause miscarriage or still born even if the mom has not gotten the shot, but is close to someone who got the shot. Those who got the shot and breast feed, may give the baby more bad ingredients. Coconut/eggs/breast feeding/mom taking a multiple vitamin and good oils/minerals/probiotic like Orthobiotic and being gluten free/Vit D3/sunlight may prevent depression/low thyroid in the mom due to low nutrients from the baby draining them out of a mom and gluten may not let nutrients absorb from her food/supplements.
4 0 Reply • Share ›

> **D.Plorable** ↗ Wendy Allen
> 21 days ago
> My friends in California asked why they were going to stick their newborn with the Hep B shot. After the "professionals" hemmed and hawed a bit they got an MD who said "well he could be sexually assaulted". (!). There is NO reason to stick the baby other than to get them used to it. The slip and fall hack lawyers and career Creatures of Government who run the Cali legislature have no basis for making any such "scientific" judgements. They make meth a citation, the police can't even make an arrest of dangerously unstable people.
> 1 0 Reply • Share ›

Rob DF
22 days ago edited
Tylenol is fine but beware of fish oil which carries a HUGE warning for pregnant women!
3 0 Reply • Share ›

Ricky Ricardo
22 days ago
...and the asbestos in their baby powder was absolutely safe - right? Oh, wait! They had to pay out a substantial amount of $$$ on that one! Scum sucking evil liars and deceivers - all of them!
https://www.asbestos.com/ne...
2 0 Reply • Share ›

Mary Johnson
19 days ago
The Fed judge was appointed by Bill Clinton. Need I say more?
1 0 Reply • Share ›

Alison
19 days ago
I wonder what tapes they' ve got on judges. Their rulings are so "surprising" sometimes.
1 0 Reply • Share ›

Darby O'Gill
19 days ago
Tylenol ? Perhaps that's just a decoy to take the spotlight off of.....the many vaccines given to infants and small children !!
1 0 Reply • Share ›

jann
20 days ago
The Southern District of NY has not been kind to the truth. It seems that a lot of these lawsuits are more successful in other parts of the U.S. Women used to be told not take any pharmaceutical during pregnancy. Was the American College of OB/GYNS paid to promote Tylenol as safe just like with the COVID shot?
1 0 Reply • Share ›

Ektor
21 days ago
Another paid off judge.
1 0 Reply • Share ›

Critical Thinker
22 days ago
There is no non-toxic amount of acetaminophen except for none at all.
1 0 Reply • Share ›

vgupta123
22 days ago
The bigger risk is indeed from Tylenol taken by babies, not the one taken during pregnancy. Yet that issue was not a part of the lawsuit. Not sure why.
1 0 Reply • Share ›

Polly Green
22 days ago
They're going to need, oh maybe...75 years?
1 0 Reply • Share ›

rti1211

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